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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,286	03/12/2004	Rajagopal Bakthavatchalam	02-090-Z (NEU-02-090-Z)	8664

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,286	BAKTHAVATCHALAM ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *223-237* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *223-226 and 228-236* is/are rejected.

7)☒ Claim(s) *227 and 237* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks and Declaration under 37 C.F.R. § 1.132, filed on 11 October 2007 have been acknowledged and duly made of record.

Applicants' extensive disclosure and explanation via the Bonache et al. article, the High Throughput Screening (HTS), Pain Models, Exhibit C, CAFC, etc. has been thoroughly considered but is not found persuasive.

The fact of matter is that in instant claim 227 of the instant claims disclose a chemical structure moiety drawn to a capsaicin receptor antagonist.

In the alternative, enablement for this core moiety may be reasonably considered based on the limitations of instant base claim 223, but enablement for any and all variable constituents as disclosed in instant claim 227 do not present substantial evidence of enablement.

Applicants' current invention is drawn to an assay of which applicants claim a method of treating. However, assays are not methods by which a functional administration and protocol may directly treat pain as disclosed. The amendments to instant claim 223 are incidental and routine to the process of assaying and not to treating pain in a mammal. Accordingly, this is also the case for all claims dependent from independent claim 223.

Particularly, the application merely provides an assay method for screening compounds useful in the claimed invention. However, a screening method for therapeutic compounds is especially considered as sufficient guidance and direction for the skilled artisan to arrive at such compounds which would be useful in the claimed method. The art of finding a chemical compound that inhibits or binds to a particular site is substantially unpredictable See University of Rochester v. G.D. Searle &Co. 69 USPQ 2D 1886, wherein the court states "The same is not

necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, ..." Attention is also directed to General Electric Company v. Wabash Appliance Corporation et al 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: the vice of a functional claim exists not only when a claims is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outline[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first or second paragraph. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted General Electric Company v. Wabash Appliance Corporation et supra, at 468. Particularly apropos to the present application is the following statement by the Supreme Court in Brenner v. Manson, 833 O.G. 1349, 148 USPQ 689, 696:

"But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. '[A] patent system must be related to the world of commerce rather than to the realm of philosophy.'"

The Declaration filed on 11 October 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the U.S.C. 112, 1st paragraph rejection. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the U.S.C. 112, 1st paragraph rejection reference to either a constructive reduction to practice or an actual reduction to practice.

Thus, the addendum of assay steps in instant Claim 223 are not considered as sufficient guidance and direction for enabling the full scope as claimed.

In Wands, the CAFC wrote that "a determination [regarding undue experimentation] must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff. Applicants' further assert that it is evident that a person of ordinary skill in the art can practice the present invention without undue experimentation.

Again, these comments are considered but are not found persuasive. On the contrary, experimentation would be undue based on the absence of any explanation clearly pointing out enablement for all moieties disclosed in instant claim 227 with all variations of constituents.

In this instant, the burden lies with the applicants' to provide reasoning as to why the scope of the current invention would not constitute undue experimentation. It would not be apparent to the skilled artisan that any and all moieties of the core structure as disclosed in instant claim 227 would be enabled in view of methods drawn to assaying/screening.

Thus, for the reasons of record, the 112, 1st paragraph rejection is maintained.

Objection

Dependent claims 227 and 237 are also objected to as being dependent upon a rejected base claim. To overcome this objection, applicants should re-write said claims in an independent form and include the limitations of the base claim and any intervening claim.

Claim Rejections- 35 USC 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 223-226 and 228-236 are rejected under 35 U.S.C. 112, first paragraph, because the specification, white being enabling for treating pain with a capsaicin receptor antagonist derived from diaryl piperazine compounds disclosed in claims 227 and 237, does not reasonably provide enablement for other capsaicin receptor antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue

experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating pain in a mammal, the method comprising administering to the mammal a therapeutic dose of a capsaicin receptor antagonist that is not a capsaicin analogue.

The relative skill of those in the art is generally that of a Ph.D. or M.D. The present invention is unpredictable unless experimentation is shown for the other capsaicin receptor antagonists beside the ones disclosed in claims 227 and 237. Unpredictability is also due to the myriad of degrees of neuropathic pain, i.e., pain thresholds, which vary from individual to individual.

Further, treatment of pain in a mammal is not determined by the process of assaying. Treatment of pain is determined by actual method and intended functions of use.

The breadth of the claims

The claims are very broad and inclusive to all capsaicin receptor antagonists other than capsaicin analogues. The metes and bounds of the claims in comparison with the central subject matter of the current invention are inadequate, that the claimed invention is not specifically

elucidated in the instant specification.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of diaryl piperazine compounds of the formula disclosed in claims 227 and 237.

No working examples showing other capsaicin receptor antagonists other than capsaicin analogues were effective in treating pain.

Instant examples 18a through 18e of applicants' specification disclose models of empirical examples and/ or standard well-established procedures. The specification states that the following protocols can be used to determine the degree of pain relief and sedation (pg 123); however the specification fails to specifically elucidate the particular model or processes disclosed in regard to claimed invention. Pain models generally have significant factors and susceptibilities that are of such a subjective nature that experimentation would be undue and burdensome. Furthermore, there is nothing in the instant specification which presents the proper guidance necessary commensurate in the scope of enablement for claimed invention.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

SHENGJUN WANG
PRIMARY EXAMINER